agents, vitamins, wound healing agents, botanical substances, fungicides, fertilizers, and combinations of the preceding.

A1 cancel

B

50. The method of claim 40 where the active agent is substantially fat soluble.

REMARKS

The application as originally filed on February 1, 2000, contained 29 claims, two of which are independent (claims 1 and 18). In an office action dated December 8, 2000, the examiner rejected claims 1-27. The office action made no reference with respect to claims 28 and 29. The claims have not been amended prior to this response.

By response to this office action, applicant has canceled claims 1-29, and has added new claims 30-50. Claims 30-50 are therefore pending in the present application.

No new matter has been added by the amendment and in the new claims, full support being found throughout the originally-filed specification.

Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 8 under 35 U.S.C. § 112, second paragraph, because of several perceived informalities. By this amendment, claim 8 has been canceled and this rejection is now moot. Accordingly, applicant respectfully requests that the rejections under 35 U.S.C. § 112 be withdrawn.

Rejection Under 35 U.S.C. § 103

The examiner has rejected claims 1-27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,849,240 to Miller et al. and U.S. Patent 5,958,452 to Oshlack et al. By this amendment, applicant has canceled claims 1-29 and this rejection is now moot. Further, applicant submits that neither Miller or Oshlack, alone or in combination, would not have made the invention (as presently claimed) obvious to one of ordinary skill in the art. Accordingly, applicant respectfully requests that the rejections under 35 U.S.C. § 103 be withdrawn.

The Invention

The invention relates to sustained-release particles and methods of making the same. Claims 30 of the invention, and all claims dependent therefrom, is limited to encapsulated particles having one or more active agent in an amount of at least about 80% by weight of the total composition. In preferred embodiments, the encapsulated particle is a sustained-release particle (claim 30).

Claim 39 and all claims dependent therefrom are limited to a process of making encapsulated particles having one or more active ingredients in an amount of at least about 80% by weight of the total composition. With respect to the embodiments in claims 36 and 46, the compound is mixed in the high-shear mixer at a speed of between about 400 rpm and about 3000 rpm. In the embodiment of claim 40, the process of the invention is faster, simpler, and more efficient, because the method is performed without milling the encapsulated particles before the encapsulated particles are discharged. In the embodiment of claims 34 and 45, the compound is mixed without using a microwave as a ancillary heat source.

The References

Miller is directed to a method of preparing sustained release pharmaceutical compositions. Miller fails to teach a composition, or method of preparing a composition, that is limited to comprising an active agent in an amount of at least about 80% by weight of the total compound. Instead, teaches active ingredients in the following amounts: 55% by weight morphine sulfate (Table 1, Example 5, Example 6,); 60% by weight morphine sulfate (Table III, Table V,); 50% by weight tramadol hydrochloride (Example 7); and 75% by weight tramadol hydrochloride (Example 8).

With respect to claim 36 of the instant invention, Miller is further distinguishable because Miller fails to teach the claimed limitation of mixing in a high-shear mixer at a speed of between about 400 rpm and about 3000 rpm to form a encapsulated particle.

Oshlack fails to teach the claimed limitation of an active agent in an amount of at least about 80% by weight of the total encapsulated particle. Instead, teaches active ingredients in the following amounts: 50% (Table 9, 10), 25% (Table 11, 12, 13), 31% (Table 14), 10% (Table 17, 18, 19,), 53% (Table 27), and 44% (Table 28).

Oshlack also fails to teach the claimed limitation of mixing in a high-shear mixer at a speed of between about 400 rpm and about 3000 rpm to form a encapsulated particle. Instead, Oshlack repeatedly teaches mixing at a speed of 100 rpm.

Applicants Position Regarding the Patentability of the New Claims

It is respectfully submitted that the references cited by the office fail to establish a *prima facie* case that the invention as presently claimed is obvious pursuant to 35 U.S.C. §

103. To establish a *prima facie* case, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference or references, when combined, must teach or suggest all the claim limitations. M.P.E.P. 706.02(j), citing, In re Vaeck, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991). Additionally, the teaching or suggestion to make the claimed invention must be found in the prior art and not based on applicant's disclosure. MPEP §2124.

Miller and Oshlack, when combined, fail to teach or suggest the claim limitations of a encapsulated particle having an active agent in an amount of at least about 80% by weight of the total encapsulated particle (all claims), or mixing a core material and oil in a high-shear mixer at a speed of between about 400 rpm and about 3000 rpm to form an encapsulated particle (claims 36, and 46).

CONCLUSION

For the reasons set forth above, applicant respectfully submits that all of the claims remaining in the application are now in condition for allowance. Accordingly, reconsideration, reexamination and allowance of all claims are requested.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 19-2090.

Respectfully submitted,

SHELDON & MAK
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Date: 5-8-01

By _____
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MARK-UP COPY OF THE CLAIM SET

1. (Canceled)
2. (Canceled)
3. (Canceled)
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22. (Canceled)
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24. (Canceled)
25. (Canceled)
26. (Canceled)
27. (Canceled)
28. (Canceled)
29. (Canceled)

30. A pharmaceutical compound comprising:
    a) a core material comprising one or more than one active agent, the active agent comprising at least about 80% by weight of the total composition;
    b) an oil having a melting point above about 110 ° F; and
    c) where the core material and oil are mixed in a high-shear mixer to form a encapsulated particle.

31. The compound of claim 30, where the oil is a hydrogenated vegetable oil with a melting point range of between about 145° F and about 160° F in an amount of about 5% or less than 5% by weight of the total compound.

32. The compound of claim 30, where the encapsulated particle is a sustained-release particle.

33. The compound of claim 30, where the mixer does not comprise a chopper.

34. The compound of claim 30, where the compound is mixed without using a microwave as a ancillary heat source.

35. The compound of claim 30, where the mixing is performed with a mixer comprising a screw type auger shaft.

36. The compound of claim 30, where the compound is mixed in the high-shear mixer at a speed of between about 400 rpm and about 3000 rpm.

37. The compound of claim 30, where the compound is mixed in the high-shear mixer at a speed of between about 600 rpm and about 2000 rpm.

38. The compound of claim 30 where the active agent comprises a compound selected from the group consisting of ace-inhibitors, anti-anginal drugs, anti-arrhythmias, anti-asthmatics, anti-cholesterolemics, anti-convulsants, anti-depressants, anti-diarrhea preparations, anti-histamines, anti-hypertensive drugs, anti-infectives, anti-inflammatory agents, anti-lipid agents, anti-manics, anti-nauseants, anti-stroke agents, anti-thyroid preparations, anti-tumor drugs, anti-tussives, anti- uricernic drugs, anti-viral agents, acne drugs, alkaloids, amino acid preparations, anabolic drugs, analgesics, anesthetics, angiogenesis inhibitors, antacids, antiarthritics, antibiotics, anticoagulants, antiemetics, antiobesity drugs, antiparasitics, antipsychotics, antipyretics, antispasmodics, antithrombotic drugs, anxiolytic agents, appetite stimulants, appetite suppressants, beta blocking agents, bronchodilators, cardiovascular agents, cerebral dilators, chelating agents, cholecystokinin antagonists, chemotherapeutic agents, cognition activators, contraceptives, coronary dilators, cough suppressants, decongestants, deodorants, dermatological agents, diabetes agents, diuretics, emollients, enzymes, erythropoietic drugs, expectorants, fertility agents, fungicides, gastro-intestinal agents, growth regulators, hormone replacement agents, hyperglycemic agents, hypnotics, hypoglycernic agents, laxatives, migrain treatments, mineral supplements, mucolytics, narcotics, neuroleptics, neuromuscular drugs, non-steroidal anti-inflammatory drugs, nutritional additives, peripheral vaso-dilators, polypeptides, prostaglandins, psychotropics, renin inhibitors, respiratory stimulants, steroids, stimulants, sympatholytics, thyroid preparations, tranquilizers, uterine relaxants, vaginal preparations, vaso- constrictors, vago-dilators, vertigo

agents, vitamins, wound healing agents, botanical substances, fungicides, fertilizers, and combinations of the preceding.

39. The compound of claim 30 where the active agent is substantially fat soluble.

40. A method of making encapsulated particles comprising a pharmaceutical compound, the method comprising the steps of:

a) dispersing a core material comprising one or more than one active ingredient in an amount of at least about 80% by weight of the total compound into a high-shear mixer;
b) adding an oil with a melting point above about 110°F to the mixer;
c) melting the oil;
d) mixing the melted oil with the core material to form encapsulated particles;
e) allowing the encapsulated particles to cool; and
f) discharging the encapsulated particles.

41. The method of claim 40, where the method is performed without milling the encapsulated particles before the encapsulated particles are discharged.

42. The compound of claim 40, where the oil is a hydrogenated vegetable oil with a melting point range of between about 145° F and about 160° F in an amount of about 5% or less than 5% by weight of the total compound.

43. The method of claim 40, where the encapsulated particle is a sustained-release particle.

44. The method of claim 40, where the mixer does not comprise a chopper.

45. The method of claim 40, where the compound is mixed without using a microwave as a ancillary heat source.

46. The method of claim 40, where the mixing is performed with a mixer comprising a screw type auger shaft.

47. The method of claim 40, where the compound is mixed in the high-shear mixer at a speed of between about 400 rpm and about 3000 rpm.

48. The method of claim 40, where the compound is mixed in the high-shear mixer at a speed of between about 600 rpm and about 2000 rpm.

49. The method of claim 40 where the active agent comprises a compound selected from the group consisting of: ace-inhibitors, anti-anginal drugs, anti-arrhythmias, anti-asthmatics,

anti-cholesterolemics, anti-convulsants, anti-depressants, anti-diarrhea preparations, anti-histamines, anti-hypertensive drugs, anti-infectives, anti-inflammatory agents, anti-lipid agents, anti-manics, anti-nauseants, anti-stroke agents, anti-thyroid preparations, anti-tumor drugs, anti-tussives, anti- uricernic drugs, anti-viral agents, acne drugs, alkaloids, amino acid preparations, anabolic drugs, analgesics, anesthetics, angiogenesis inhibitors, antacids, antiarthritics, antibiotics, anticoagulants, antiemetics, antiobesity drugs, antiparasitics, antipsychotics, antipyretics, antispasmodics, antithrombotic drugs, anxiolytic agents, appetite stimulants, appetite suppressants, beta blocking agents, bronchodilators, cardiovascular agents, cerebral dilators, chelating agents, cholecystokinin antagonists, chemotherapeutic agents, cognition activators, contraceptives, coronary dilators, cough suppressants, decongestants, deodorants, dermatological agents, diabetes agents, diuretics, emollients, enzymes, erythropoietic drugs, expectorants, fertility agents, fungicides, gastro-intestinal agents, growth regulators, hormone replacement agents, hyperglycemic agents, hypnotics, hypoglycernic agents, laxatives, migrain treatments, mineral supplements, mucolytics, narcotics, neuroleptics, neuromuscular drugs, non-steroidal anti-inflammatory drugs, nutritional additives, peripheral vaso-dilators, polypeptides, prostaglandins, psychotropics, renin inhibitors, respiratory stimulants, steroids, stimulants, sympatholytics, thyroid preparations, tranquilizers, uterine relaxants, vaginal preparations, vaso- constrictors, vago-dilators, vertigo agents, vitamins, wound healing agents, botanical substances, fungicides, fertilizers, and combinations of the preceding.

50. The method of claim 40 where the active agent is substantially fat soluble.